37

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,323	12/31/2003	Rey-Yuh Wu	03-1119	1770

20306 7590 02/28/2006

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,323	WU ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, as specifically drawn to a composition for inhibiting carcinogenesis and metastasis comprising a therapeutically effective amount of an Astragalus radix and Codonopsis pilosulae radix mixed extract, classified in class 530, subclass 370.

II. Claims 7-9 and 13-20, as specifically drawn to a method of producing the Astragalus radix and Codonopsis pilosulae radix mixed extract comprising coextracting Astragalus radix and Codonopsis pilosulae radix in water, classified in class 436, subclass 178.

III. Claims 10-12, as specifically drawn to a method of producing Astragalus radix and Codonopsis pilosulae radix mixed extract comprising extracting Astragalus radix and Codonopsis pilosulae radix with water and ethanol, classified in class 436, subclass 178.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method of producing Astragalus radix and Codonopsis pilosulae radix mixed extract comprising extracting Astragalus radix and Codonopsis pilosulae radix with water (Group II) and method of producing Astragalus radix and Codonopsis pilosulae radix mixed extract comprising extracting Astragalus radix and Codonopsis pilosulae radix with water and ethanol (Group III) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material, e.g., water or water/ethanol solvent system. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups II and III are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups II and III.

The inventions of Group II-III and I are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition comprising a mixed extract of Astragalus radix and Codonopsis pilosulae radix can be made by a materially different method wherein the method involves extracting the mixed extract from either water or a water/ethanol solvent system each of which would have different chemical properties.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

During a telephone conversation with Blair Hughes on 02/16/2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statements filed on 4/2/2004 and 9/19/2005 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kexin et al. (Chinese Journal of Combined Traditional and Modern Medicine 1999; 19: 11-13, translated).

Kexin et al. teach the clinical effects of Shenqi Fuzheng in treating gastric cancer (abstract). With regards to Shenqi Fuzheng, the reference teaches that Shenqi Fuzheng consists of Huang Qi (astragalus root) and Dang Shen (pilose asiabell root) (page 2 of translation, *Treatment Method*) and is produced as a solution for injection. Thus, while Kexin et al. do not explicitly teach that *Codonopsis piola* and the species thereof is also referred to DangShen, it does not appear that the claim language or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 11-13 and page 4, lines 3-5) that *Codonopsis pilosulae* is also known as Dangshen which is the dried root of *Codonopsis pilola* (Franch.) Nannf, *Codonopsis tangshen* Oliv.. or *Codonopsis pilola* (Franch.) var. modesta (Nannf.) L.T. Moreover, although Kexin et al. do not explicitly teach that *Astragalus radix* and species thereof is also referred to Huang Qi, it does not appear that the claim language or limitation results in a manipulative difference as compared to the prior art disclosure because the specification discloses (page 1, lines 10-11 and 17-20) that *Astragalus radix* is also known as Huang Qi which is the dried root of *Astragalus mogholicus or Astragalus membranaceus*. Lastly, although Kexin et al. do not specifically teach that Shenqi Fuzheng can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2004/0105902, 2004).

Chen et al. teach a composition for treating prostate cancer comprising a therapeutically effective amount of *Astragali radix* (referred to also as Huang Qi) and *Codonopsis pilosulae radix* (page 2, paragraph 0017). With regards to the composition, the publication teaches that the composition consists of weight ratio of 1:1 (page 4, 2nd column, Example 1). Chen et al. further teach that the composition may be in the form of a solution and/or tablet/capsule (page 3, 1st column, paragraph 0026). Although Chen et al. do not specifically teach that the purified *Astragali radix* and *Codonopsis pilosulae radix* are extracted from a particular species, the claims are drawn to a composition comprising the two specific extracts, e.g., *Astragali radix* and *Codonopsis pilosulae radix*. Thus, the claimed composition appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Along the same lines, while Chen et al. do not specifically teach that the composition can be used for the treatment of colon cancer, lung carcinoma or mammary carcinoma, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Therefore, NO claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Xin et al. (Zhongguo Zhong Xi Yi Jie He Za Zhi 1998; 18: 658-661, abstract in English) teach the effects of Shenqi Fuzheng injection combined with chemotherapy in treating malignant tumor of the digestive tract.

Zhao et al. (Zhongguo Zhong Xi Yi Jie He Za Zhi 2001; 21: 424-426, abstract in English) teach the effects of Shenqi Fuzheng injection on immune function in gastric carcinoma patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
2/21/06